

SECTION 6

OCT 13 2006

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K 061070**Applicant Information:**

Owner Name: Hansen Medical, Inc.
Address: 380 N. Bernardo Ave.
Mountain View, CA. 94043
Office: 650-404-5800

Contact Person: Nina Peled, PhD
Phone Number: 650 404 5834
Facsimile Number: 650 404 5901

Date Prepared: April 14, 2006

Device Information:

Classification: Class II
Trade Name: Hansen Medical Transseptal Needle and Dilator
Common name: Transseptal needle and dilator
Classification name: Trocar (21 CFR 870.1390, Product Code DRC)
Vessel Dilator (21 CFR 870.1310, Product Code DRE).

Predicate Devices:

The Hansen Medical Transseptal Needle and Dilator are substantially equivalent in intended use and method of operation to:

1. Daig Corp., BRK Transseptal Needle, pre-amendment.
2. Thomas Medical Products, Inc., Transseptal Needle/Trocar, K011727.
3. Thomas Medical Products, Inc., Catheter Introducer Set, K020090 – Vessel Dilator part of the set.

Device Description:

The Hansen Medical Transseptal Needle consists of an outer needle cannula and includes in its proximal end a female luer. The distal section is comprised of flexible thin walled tubing and contains a marker for visibility during fluoroscopy while the distal tip of the needle is ground into a beveled shape.

Hansen Medical
Transseptal Needle and Dilator

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The Hansen Medical Dilator is made of a flexible tube with a tapered end on the distal outer diameter. Attached to its proximal end is a Tuohy Borst® adapter to prevent fluid egress. The adapter includes a side port with a 1-way stopcock to provide flushing capability. The dilator also has imbedded markers at two positions on the distal end to provide visual feedback under fluoroscopy.

Intended Use:

The Hansen Medical Transseptal Needle and dilator are intended to create the primary puncture in the interatrial septum for passing an introducer and/or catheter through the septum from the right side of the heart to the left side.

Comparison to Predicate Device(s):

The Hansen Medical Transseptal Needle and Dilator have the same general intended use and similar technological characteristics as the predicate devices.

Substantial equivalence:

Based upon the indication for use, the technological characteristics and the design and engineering data provided in this pre-market notification, the Hansen Medical Transseptal Needle and Dilator have been shown to be substantially equivalent to other legally marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 2006

Hansen Medical
c/o Nina Peled, Ph.D., MBA
Vice President, Quality and Regulatory Affairs
380 North Bernardo Ave.
Mountain View, CA 94043

Re: K061070
Hansen Medical Transseptal Needle and Dilator
Regulation Number: 21 CFR 870.1390
Regulation Name: Trocar
Regulatory Class: Class II (two)
Product Code: DRC
Dated: September 1, 2006
Received: September 6, 2006

Dear Dr. Peled:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

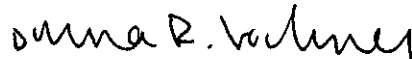
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

SECTION 5

Indications for Use

510(k) Number (if known): K061070

Device Name: Hansen Medical Transseptal Needle and Dilator

Indications for Use:

The Hansen Medical Transseptal Needle and dilator are intended to create the primary puncture in the interatrial septum for passing an introducer and/or catheter through the septum from the right side of the heart to the left side.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Hansen Medical
Transseptal Needle and Dilator

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(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K061070